IDAHO DEPARTMENT OF HEALTH & WELFARE

BUREAU OF CARE MANAGEMENT
PHARMACY

Guidelines for Prior Authorization of Prolastin ® (Alpha-1 Antitrypsin Inhibitor-Human)

Background:

Prolastin (alpha-1 antitrypsin inhibitor) is used for treatment of congenital alpha-1 antitrypsin deficiency (ATT) associated emphysema. ATT deficiency is associated with the early onset of severe pulmonary emphysema in adults. Serum levels of ATT in normal subjects are usually in the range of 130-200 mg/dl, but in ATT deficient patients with evidence of pulmonary disease, serum levels are generally less than 50 mg/dl.

There are a number of phenotypic variants for ATT deficiency. Prolastin is indicated for PiZZ, PiZ (null), or Pi(null null) phenotypes. Prolastin therapy is not considered for patients with PiMZ or PiMS phenotypes of ATT deficiency because they appear to be a low risk of panacinar emphysema.

Patients with ATT deficiency who smoke are at considerable risk for early emphysema.

Once initiated Prolastin therapy will usually continue for the remainder of the patient's life. It is recommended that recipients of alpha-1 antitrypsin therapy should be immunized against Hepatitis B. Patients with immunoglobulin antibody IgA deficiency who are known to have antibodies against IgA are recommended not to receive this therapy. These patients may experience severe anaphylaxis reactions to IgA that may be present in human alpha-1 antitrypsin inhibitor.

Medicaid Prior Authorization Criteria:

1. Patient is a non-smoker.
2. Patient is 18 years of age or older.
3. Patient must have alpha-1 antitrypsin deficiency documented by the following:
   a. Laboratory level which shows patient has a low serum concentration of alpha-1 antitrypsin (ATT) < 50 mg/dl or < 11 uM/L or < 0.8 g/L (35% of normal), which is considered the threshold thought to protect against emphysema.
   b. Must have alpha-1 antitrypsin phenotype of PiZZ, PiZ(null) or Pi(null, null).
   c. Changes in pulmonary function should be documented, including forced expiratory volume (FEV1) of between 25-65 percent of normal, or a documented decline in FEV1 of more than 80 ml/year.
4. Patient must demonstrate a positive response to continue receiving Prolastin.
5. Initial approval for Prolastin therapy may be granted for a maximum of 12 months. Dosing is limited to 60 mg/kg of patient body weight, administered intravenously every week.
6. Prior to re-authorization for continued use, written documentation of repeat PFT results is required to evaluate the client's pulmonary function status.